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ANSWER 5 OF 5 EMBASE SPYRIGHT 2002 ELSEVIER SCI. B.V. AN 2001188709 EMBASE 77. 1 Improved pharmacokinetic properties of a polyethylene glycol modified form of interferon beta. la with preserved in litro bloadtivity. AU Pepinsky P.B.; Lepage D.J.; Gill A.; Chakraborty A.; Vaidyanathan S.; Green M.; Baker D.P.; Whalley E.; Hochman P.S.; Martin P. CS F.B. Pepinsky, Department of Protein Chemistry, Biogen, Inc., 14 Cambrigde Ctr., Cambridge, MA 02142, United States. Blake Pepinsky biogen.com Cournal of Pharmacology and Experimental Therapeutics, (2001: 297/3 SO +1059 1066). F∈fs: 30 ISSN: 0022 3565 CODEN: JPETAB CYUrited States DT Cournal; Article FS 0.3.0 Fharmacology 037 Drug Literature Index 039 Pharmacy LA English English SL

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July 1998 - hepcBC.bull

Research and HCV- How YOU Can Make a Difference by Darlene Morrow, BSc

At the hepc bull we are making a concerted effort to become directly involved in our own therapies and research into HCV. We are pushing for more HCV research and ultimately a cure. With that in mind we have sent out letters to the drug companies that are directly involved in research into HCV. A copy of a similar letter appears on page 5 of this newsletter. We have sent letters to over 25 companies and will follow through, unrelentingly, until we get a response and help. We want YOU to send the letters, too. You can copy the letter here, write it in your own hand, or write a different one altogether. We must take charge of what is happening with the research and/or treatment. The more of us that get involved, the more likely we are to succeed. Let's all work together for a CURE. I am listing the companies, their addresses and a brief description of what they are researching.

1. <u>SciClone</u> Donald R. Sellers 901 Mariner's Island Blvd., San Mateo, CA, 94404 Zadaxin, Zadaxin/IFN.

ZADAXIN (thymosin alpha 1) was originally isolated from the thymus gland and is now produced through chemical synthesis. ZADAXIN has been shown to stimulate the human immune system by promotes the maturation of T cells, which are involved in the control of various immune responses.

2. <u>Schering-Plough</u>, DNAX Research Institute 901 California Ave., Palo Alto, CA, 94304-1104

Pegylated IFN, Rebetron (Intron A and ribavirin combination), Intron A, IFN/iron reduction, Rebetron in treatment naive patients, Induction Combo- high dose IFN for 30 days followed by traditional dose for 11 months.

Intron A-Interferon, Alpha-2b [Recombinant] - a water soluble alpha-interferon protein produced in recombinant E. coli containing the interferon alfa-2b gene from human leukocytes.

Pegylated (PEG) **Interferon** is a long acting **interferon** that only requires a once a week injection.

Ribavirin a guanosine analogue antiviral drug with actions against a wide variety of DNA and RNA viruses including HCV.

3. <u>Amgen</u> Gordon Binder 1840 DeHavilland Drive Thousand Oaks, CA, 91320-1789 Infergen, Maxamine (see Maxim for details)

Infergen; **Interferon** Alfacon-1; consensus **interferon**, recombinant. A non-naturally occurring, recombinant, "consensus" form of **interferon**-alpha protein derived from E. coli.

4. Amarillo Biosciences Joseph Cummins 800 W 9th Avenue, Amarillo, TX 79101-3206

Sublingual IFN, Non Oral IFN. Studying the effects of low dose oral IFN with high dose injectable IFN.

5. Nabi David J. Gury 5800 Park of Commerce Blvd. NW, Boca Raton, FL, 33487

Nabi-Civacir (human polyclonal antibodies to HCV).

6. Chiron Corporation Sean Lance 4650 Horton Avenue, Emeryville, CA, 94608

Beta IFN (recombinant).

7. <u>Interferon Sciences, Inc.</u> Mei-June Liao 783 Jersey Avenue, New Brunswick, NJ, 08901-3660

Alferon N (**Interferon** Alfa n-3). Alferon is a natural, human leukocyte-derived **interferon** alpha protein for use by injection.

8. Viragen, Inc. Gerald Smith 865 SW 78th Avenue, Suite 100, Plantation, FL, 33324

Natural Human IFN.

9. <u>Glaxo Wellcome</u> Dr. Richard Sykes Lansdowne House, Berkeley Square London W1X 6BO, UK

Wellferon (Lymphoblastoid IFN). A highly purified blend of natural human alpha interferons, obtained from human lymphoblastoid cells following induction with Sendai

virus.

10. Hoffmann-LaRoche 340 Kingsland Street Nutley, NJ 07110

Roferon-A (IFN alpha-2a, recombinant), PEG IFN Roferen: Recombinant E. coli-expressed interferon alpha-2a.

Pegylated (PEG) **Interferon** is a long acting **interferon** that only requires a once a week injection. The **interferon** has been covalently bound to polyethylene glycol and is slowly released as these covalent bonds degrade. This offers the effect of a steady level of IFN in the blood.

11. Biogen Corp. James R. Tobin 14 Cambridge Center, Cambridge, MA, 02142

Avonex Interferon beta-1a, recombinant. Produced by mammalian cells (Chinese Hamster Ovary cells) into which the human interferon beta gene has been introduced.

12. ICN Pharmaceuticals Milan Panic 3300 Hyland Avenue, Costa Mesa, CA, 92626

Ribavirin — see Schering

13. <u>Maxim Pharmaceuticals</u> Larry G. Stambaugh 8899 University Center Lane, Suite 200, San Diego, CA, 92121

Maxamine is a form of histamine, in combination that is used with Amgen's Infergen. A recent publication demonstrated that patients with chronic hepatitis C (HCV) with low levels of histamine in blood did not respond to IFN-alpha. Maxamine is a histamine analog and has been shown to enhance or synergize with cytokines such as **interferon**-alpha.

14. <u>Immunex Corporation</u> Edward V. Fritzky 51 University Street, Seattle, WA, 98101 Granulocyte-Macrophage Colony-Stimulating Factor (GMCSF) used with **Interferon**.

HepC BC

HepC AB

Investigational Research Looking for Novel Treatments for HCV

by Darlene Morrow, BSc

There are well over 20 companies doing research into the following areas:

- 1. Protease Inhibitor Therapy A protease inhibitor would be any substance which partially or completely blocks the ability of a proteolytic enzyme to carry out its activity. In HCV we have identified serine proteinases, HS3 helicase and HS5b polymerase. These enzymes are essential for viral replication.
- 2. Antisense Based Therapy Antisense oligonucleotides are molecules that are highly charged that form DNA- RNA or RNA-RNA hybrids. The hybrid formation inactivates the viral replication by preventing the transcription of HCV proteins from the HCV genome.
- 3. Ribozyme Gene Therapy RNA molecules that selectively degrade RNA, including viral RNA. When directed against HCV RNA it has the ability to destroy the virus's replicative material. These compounds are highly unpredictable and non-specific and therefore may be potentially toxic.
- 4. Vaccine Based Therapy— Using DNA-based immunization to study the immune responses against HCV.

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SAMPLE LETTER

[YOUR ADDRESS][DATE]

[RESEARCH COMPANY'S ADDRESS]

Dear Sir or Madam:

I am writing to you as a person infected with HCV. I would like to find out how my friends and I can get more involved in the clinical trials and sharing of information with regard to HCV therapy and research.

We are very interested in the work that you are doing on _____ and would like to see more clinical trials conducted here in Canada and would appreciate any direction that you can give us.

Sincerely,

[YOUR SIGNATURE]

[YOUR NAME - PRINTED OR TYPED]

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Shall We Dance?

Come support the Victoria Chapter of HeCSC. Mark the date on your calendars now: October 10, 1998 (subject to change,) place to be announced. Bring friends, and dance to the music of the band "Rukus."

Volunteers are needed for decorations and food. Please call (250) 388-4311 to sign up.

ПерС ВС

HepC AB

HCV- The Taboo Subject

Some people may have skeletons in their closets, and when I was diagnosed with hepatitis C in September 1995, mine all came back to haunt me. It was in the fall of 1977 that I first tried injection drugs—cocaine was the first drug of choice. I would classify myself as an experimenter, rather than a physically-dependent drug addict. I never learned how to inject myself, sharing needles with either my heroin-addicted boyfriend or my girlfriend. When you're young, you do some stupid things sometimes. I always thought I was being careful, though. Not careful enough. Eighteen years after I first had a needle in my arm, I learned during a routine physical exam that I was infected with hepatitis C, an insidious deadly blood-borne virus that attacks the liver. I am among the highest-risk group, which is composed of people who have shared needles to use drugs. The virus is not only spread by using intravenous drugs but also, some experts believe, by sharing the straws used to snort cocaine—a drug many North Americans in their forties and fifties have tried. Microdroplets of blood, dislodged when a coke straw bumps the delicate capillaries inside the nose, can be passed on the end of the straw. Hepatitis C is already an inner-city and drug-user epidemic. Infection among IV drug users is estimated at up to 90% and in the prison population in Canada, hepatitis C infection accounts for a third of the inmates. The virus has infected not only people who are at the lower end of the social and economic scale, but also plenty of those in the middle class. With the prevalence of

recreational drug use in the sixties and seventies, and the two- to three-decade progress of the virus, many people are just discovering now that they are infected with this stealth disease, known as "the dragon." I'm among those tax-paying, law-abiding solid citizens today paying the price for the sins of my youth. While IV drug use, past and present, is the leading cause of HCV infection, other modes of transmission are blood transfusions, tattooing, body piercing, acupuncture, accidental needle stick injures to health-care workers with a contaminated needle, manicures, pedicures, sharing razors or toothbrushes, snorting drugs, sexual contact, childbirth and breast-feeding. No matter how low the risk is, the possibility is there. I also have read that HCV has been found in stored blood from the forties. Some people go even further implying the possibility of chemical warfare, a conspiracy. Who knows for sure? I decided after a lot of pondering to tell my liver specialist at my first visit that I had used IV drugs in the past. I assumed revealing this fact would benefit my care and their research. I didn't have to reveal my sordid history, since the virus was possibly caused by the injection of gamma globulin that I had received, after I contracted hepatitis B, two years prior to any drug use. That makes it acceptable in the eyes of the society. I am disturbed by this self-righteous attitude a lot of people have towards ex-drug users and others who don't fit into society's perfect vision. My mistakes occurred over twenty years ago! Do I have to pay for those mistakes with my life? I am no less deserving of medical care than anyone else. I would like people to understand the stigma involved with being an ex-drug user. I have honestly admitted to my past history of two years of illegal drug experimentation to my doctors. It seems irrelevant to the doctors that I had received a blood product prior to any drug use. The label is there and I'm stuck with it. It doesn't matter that I used drugs twenty years ago either. It is frustrating to always be on my guard, that I am not being overlooked for inclusion in a treatment program because there are other people "more deserving." I have come forward to dispel the perception of former drug-users. With the support of my immediate family, I have been able to forgive myself for my past transgressions. I am not that person anymore. People can change to better themselves. I am trying to see the positive out of the negative. What I have learned from my past is compassion and tolerance for others. I have been watching the news and reading the paper daily regarding the Krever report and the tainted blood issue. I sympathize with the people who did receive infected transfused blood and hope there is a light at the end of the tunnel, and you are all compensated accordingly. My point is to show you the other side of the coin. I just want everyone to walk in my shoes and understand my feelings. Injustice is when the mere mention to someone that I probably acquired HCV through IVD use is met with a certain demeanour of repugnance. It is like I get pushed back twenty years over and over. I am suddenly stuck in a mold that no matter what I'm like today, it doesn't seem to make a difference with a person's attitude towards me. Especially a doctor's opinion. I can't change my past. I need compassion and support just like anyone else. It is important to concentrate on enlightenment in education, to speak out for research money for a cure for HCV, and to not exclude people from treatment just because they may have acquired HCV through drug use. These issues are just as important as the fight for compensation for the "innocent victims." More research should be done for the numerous people that got hepatitis through other means. The blood scandal is bringing to the forefront the disease which was not talked about, and hopefully, through the press it is getting, there will be more funds for research. Today I am a respectable, middle class, 41-year-old wife and mother of two sons, 8 and 16, presently living in Toronto, Ontario. I am university-educated, and over the years I have worked as a nutritional consultant. My volunteer community service has involved being a parent teacher's assistant in primary classes, a French language teacher's parent assistant for grades 7-9, a Beaver leader and group secretary for Scouts Canada, a Sunday school teacher and church secretary. I really want more than anything for people to get a different view of those HCV sufferers who may have acquired the disease from past drug use. A majority of us experimented decades ago and are only now manifesting symptoms of the disease. We are the baby boomers with respectable positions in society today. We have various careers including teaching, social work, computing, office work and truck driving. We deserve just as much respect from doctors and availability to treatment as the next person. No matter how we contracted this deadly virus, whether through blood transfusion, unclear reasons, or past IV drug use like myself, we are all in the same predicament. We are a large group of Canadian HCV sufferers who deserve mutual respect and all our voices to be heard. Feel free to e-mail me.

I will not judge you but support you in your struggle not only with this "dragon" but with the acceptance of you as a person. You are not alone in this battle.

Smilin' Sandi

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HepC AB

FOUR HCV CLINICAL TRIALS IN BC

Dr. Anderson at 604.876.5122

1. **Interferon** and Ribavirin Combination Therapy

Non-responders or relapsers to **interferon** alone are being studied in a combination therapy trial using 3 million units of **interferon** injected three times a week (which the patient pays for) and 1000-1200 mg of ribavirin orally twice a day (which is paid for by the drug company.) THIS STUDY WILL BE CLOSING SOON.* This is now done on compassionate grounds, i.e., it isn't a study.

2. Amantadine Therapy in Combination with **Interferon** in non-responders or relapsers.

This trial is looking at amantadine in the treatment of HCV. THIS IS AN OPEN STUDY.

3. PEG Interferon Trial

Pegylated (PEG) **Interferon** is a long acting **interferon** that only requires a once a week injection. Patients are randomly assigned to one of two therapies: a) PEG **interferon** injection once a week OR b) induction of **Interferon** at a high dose for one month followed by the standard dose of 3 million units three times a week for the duration of the trial. This trial is for a period of one year and the cost of the drug is paid for by the drug company and is OPEN to naive patients only (not previously treated with **interferon**).

4. Low Dose Maintenance Schedule with Interferon

This trial will begin sometime in the new year and will look at low dosage maintenance therapy of **interferon**.

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New Vice Chairs

David Smith was chosen Vice-Chair of the National Board of HeCSC

Dr. C.D. Mazoff was elected Vice-Chair of the Victoria Chapter of HeCSC.

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Marjorie Harris Re-elected President of HepCURE by Darlene Morrow

Marjorie Harris was recently elected president of HepCURE for a second term. The Hepatitis C United Resource Exchange (Hep CURE) is a registered non-profit organization. The executive has five members drawn from the hepatitis c and academic communities. Their application for federal charitable status is still in process. HepCURE has a research list on the internet, indexes of articles on HCV, and provides educational and support group activities. The internet research group is a closed list of scientists from various specialities that review the latest journal articles and discuss the connections between them in the hope of finding a cure for HCV.

HepCURE's mission statement is to cultivate an international network promoting Hepatitis C education, support and research.

Donations go to cover internet and telephone costs at present. In the future they would like to rent a small office space in Vernon so that volunteers can help with the ongoing work and to give a public focal point to work from so that funds can be generated to aid HCV researchers directly as is done similarly by other large campaigns for cancer and diabetes.

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Hepatitis C Society of Canada Message from the Chairman of the Board of Directors

June 17, 1998 The last few weeks have been particularly busy with compensation issues. This message is being sent to HeCSC Board Members and Chapter Heads as a way in which to keep HeCSC volunteers and members up-to-date with the issues. It is expected that an update will be sent on a bi-weekly basis to all of you for the next couple of months. Jeremy Beaty, HeCSC Chair, continues to lead the organisation on compensation matters. Jeremy Beaty and David Smith, HeCSC Vice-President (Victoria Chapter Head) attended a meeting in late May in Edmonton of the Federal Provincial Territorial (F P T) Working Group on Hepatitis C. No decisions were made at this meeting; however, it was important for HeCSC to be there. Thanks to the Edmonton Chapter for organising a small rally during these meetings. It was widely covered by the press. HeCSC has begun to investigate the possibility of establishing a HepC Carrier Compensation Advisory Group to provide the HeCSC Board with input. More information will be available in the near future. HeCSC has been invited to participate in an Expert Panel hosted by Health Canada.

Epidemiologists will present their assessment of the number of individuals infected with Hep C from blood transfusions. Jeremy Beaty, HeCSC Board Chair, and Tim McClemont, HeCSC Executive Director, will be representing HeCSC at these meetings later this week. The Kitchener-Waterloo Chapter held an informal, private meeting with The Honourable Alan Rock last week. Chapter Head Carolyn Cavaney lead the HeCSC delegation for this meeting, where personal stories of the challenges people faced as a result of Hep C were recounted to the Minister, Jeremy Beaty and other members of the HeCSC Compensation Task Force have met with officials of the Ontario provincial government to discuss and further clarify the position of the Ontario government on compensation for all persons infected with HepC as a result of tainted blood. Jeremy Beaty and Durhane Wong-Reiger (CHS) appeared on Mike Duffy's Sunday Edition June 7th to discuss the issue of compensation. Joey Hache began his Cycle for Conscience on June 15th in Nova Scotia. He will be eveling across Canada to increase public awareness about Hep C. He is hoping to collect One Million signatures from Canadians coast-to-coast. More details will be available in the June edition of the HeCSC newsletter. The Webpage to track his progress is: www.igs.net/~reflect/joey/schedule.htm Debi Ripley, HeCSC Board Member from New Brunswick, met with the NB Premier and Health Minister recently. It was a productive meeting and we are looking forward to a public announcement of support for compensation of all persons infected with Hep C as a result of

Jeremy Beaty, HeCSC Chair

the HeCSC national office.

HepC BC

tainted blood. That's the news for now! If you wish to discuss any of the above, please feel free to contact

HepC AB

COMING UP:

Victoria HeCSC Meetings: Last Wednesday of each month 1-3 PM, and again at 7-9 PM, St. John the Divine Church Lounge, 1611 Quadra St. (Entrance through the rear, marked Annex) NEXT MEETING: July 29th.

Penticton HeCSC Meetings: Third Thursday of every month, 7-9 PM, Penticton Health Unit rooms. NEXT MEETING: July 16th.

Kelowna HeCSC Meetings: Last Saturday of every month, 1-3 PM, Rose Avenue Education Room in Kelowna General Hospital. NEXT MEETING: July 25th.

Nanaimo HeCSC Meetings: Second Thursday of every month, 7 PM, Health Unit-Central Vancouver Island, 1665 Grant St. NEXT MEETING: July 9th.

Vancouver CLF Support Group Meetings: Second Thursday of every month, 7:30 PM, Nurses' Residence of VGH (12th and Heather). Signs will direct you. NEXT MEETING: July 9th, Contact the CLF 681-4588 or Herb 241-7766.

Sunshine Coast Support Group Meetings: First Thursday of each month, 7:30 PM, Coast Garibaldi Health Unit in Gibsons. NEXT MEETING: July 2nd. Contact Carol: 886-4298 - ryker'a cheerful.com -

Vernon HepCURE Meetings: 1st Tuesday 12-2 PM and 3rd Tuesday 6-8 PM of each month, the People Place, 3402 - 27th Ave. NEXT MEETING: July 21st. Contact: Marjorie 558-7488 · www.junction.net hepcure ·

Enderby HepCURE Meetings: Last Sunday of each month 2-4 PM for High Tea, The Raven Gallery, 701 George St. NEXT MEETING: June 28th.Contact: Marjorie (250)558-7488 www.junction.net/hepcure

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